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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/583,316

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Alain Aaron

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CANTOR COLBURN, LLP
20 Church Street
22nd Floor
Hartford, CT 06103

EXAMINER

FISHER, ELANA BETH

ART UNIT

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3733

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/583,316	Applicant(s) AARON, ALAIN	
	Examiner ELANA B. FISHER	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☒ Claim(s) 14 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 June 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>06/14/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claim 14 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot be dependent on a plurality of claims (i.e. 3 and 10 through 13) at the same time. See MPEP § 608.01(n). Accordingly, the claim will not be further treated on the merits.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-3 and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Huang (U.S. Publication 2004/0193273).

a. Regarding claim 1, Huang discloses an intervertebral disc prosthesis comprising two rigid half-shells in the form of cups or plates (1, 2) which are each intended to be fixed to one of two vertebrae adjacent to an intervertebral disc to be replaced. The two half-shells enclose a compression pad (3) made of at least two materials of different hardness (Paragraph [0034] – Paragraph [0038]), wherein one of the two half-shells (2) comprises, in its central zone, a shaft (see diagram provided) which is oriented toward the second half-shell (1), with the second half-shell comprising, in its central zone, a stud (14) whose cross section is smaller than that of the shaft and which is

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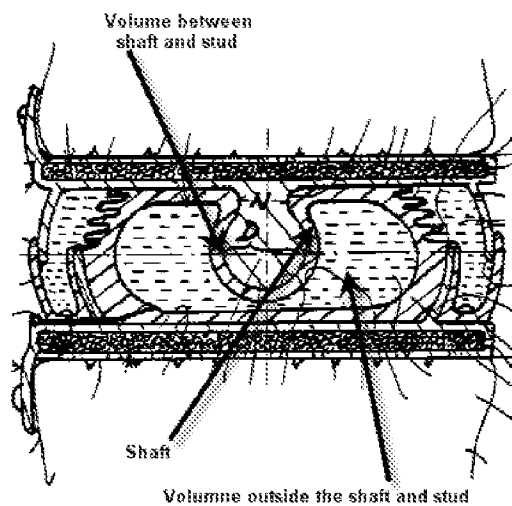
oriented toward the first half-shell and is engaged in the shaft of the latter, and additionally a sum of the lengths of the shaft and of the stud (14) is greater than the distance between the two half-shells (1, 2), with the compression pad being disposed between the two half-shells, including a volume (see diagram provided) situated between the shaft and the stud.

b. Regarding claim 2, the volumes disposed outside and inside of the shaft (see diagram provided), respectively, are filled with compressible materials of different hardness (Paragraph [0034] – Paragraph [0038]).

c. Regarding claim 3, the compressible material situated outside the shaft is harder than the material situated inside the shaft (Paragraph [0034] – Paragraph [0038]).

d. Regarding claim 8, each half-shell (1, 2) comprises, on its outer face, points (121, 221) intended to promote its fixation to a vertebra (FIG 1).

Regarding the above claims, see figure 1 and the diagram provided on below.



Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 5-7 and 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huang (U.S. Publication 2004/0193273) as applied to claims 1 and 3 above.

a. Regarding claim 5, Huang discloses an intervertebral disc prosthesis according to claim 3 above, however fails to disclose the material of the compression pad that is situated outside the shaft (see diagram provided). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the compressible material situated outside the shaft be a synthetic material of the polycarbonate urethane type, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

b. Regarding claim 6, Huang discloses an intervertebral disc prosthesis according to claim 3 above, however fails to disclose the material of the compression pad that is situated inside in the shaft (see diagram provided). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the compressible material situated inside the shaft be a mixture of two-component silicone elastomer and of an encapsulating copolymer whose blowing agent is isobutane, since it has been held to be within the general skill of a worker in the art to select a known

material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

c. Regarding claim 7, Huang discloses an intervertebral disc prosthesis according to claim 1 above, however fails to distinctly state that the two half-shells (1, 2) are made of a titanium based alloy (Paragraph [0025]). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the two half-shells be made of a titanium-based alloy, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

d. Regarding claim 11, Huang discloses an intervertebral disc prosthesis according to claim 1 above, however fails to disclose that the stud (14) and shaft (see diagram provided) have a trapezoidal cross section. It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the stud and shaft with a cross-section having a trapezoidal shape, since applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing a forming edge in the heating portion or clamp. *In re Dailey and Eilers*, 149 USPQ 47 (1966).

e. Regarding claim 12, Huang discloses an intervertebral disc prosthesis according to claim 1 above, however fails to disclose that the stud and the shaft have a non-circular cross-section. It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the stud and shaft with a cross-section

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having a non-circular shape, since applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing a forming edge in the heating portion or clamp. *In re Dailey and Eilers*, 149 USPQ 47 (1966).

Regarding the above claims, see the figures corresponding to claims 1 and 3 above.

6. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Huang (U.S. Publication 2004/0193273) as applied to claim 3 above, and further in view of Gauchet (U.S. Patent 6,582,468).

a. Regarding claim 4, Huang discloses an intervertebral disc prosthesis according to claim 1 above, however fails to disclose the Shore-A hardness of the compressible material inside and outside of the shaft. Gauchet discloses an intervertebral disc implant with a compressible pad that has a Shore-A hardness of between 60 and 100 (Column 3, lines 7-8). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the Shore-A hardness of the compressible material outside of the shaft to be between 60 and 100, and additionally the Shore-A hardness of the compressible material inside the shaft to be between 25 and 30, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

7. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Huang (U.S. Publication 2004/0193273) as applied to claim 1 above, and further in view of Hedman et al. (U.S. Patent 4,759,769).

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a. Regarding claim 9, Huang discloses an intervertebral disc prosthesis according to claim 1 above, however fails to disclose that there are lugs on the face of each half-shelf (1, 2). Hedman et al. disclose an intervertebral disc prosthesis that comprises lugs (46) on the inner face of two half-shells (30, 50). It therefore would have been obvious to one skilled in the art to modify the intervertebral disc prosthesis taught by Huang with the addition of lugs to the inner face of the half-shells, as is taught by Hedman et al. because the lugs provide the advantage of aiding in securing the half-shells to the vertebrae, which in-turn aid in attachment and implantation of the compression pad to the intervertebral disc space.

Regarding the above claim, see the figures corresponding to claim 1 and figure 1 in Hedman et al.

8. Claims 10 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huang (U.S. Publication 2004/0193273) as applied to claim 1 above, and further in view of Errico et al. (U.S. Publication 2003/0074067).

a. Regarding claim 10, Huang discloses an intervertebral disc prosthesis according to claim 1 above, however fails to disclose the means by which the stud (14) is fixed to the half-shell (1). Errico et al. discloses an intervertebral disc prosthesis with a stud (28) that is fixed to a half-shell (10) by being screwed into a through-hole (26). It therefore would have been obvious to one skilled in the art to modify the prosthesis taught by Huang with the fixation means of screwing the stud into the top of the half-shell, as is taught by Errico et al. because screwing the stud into the half-shell is an alternative fixation means which accomplishes the goal of attachment of the stud, while keeping the

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intervertebral disc prosthesis functionally and mechanically analogous to another fixation means.

b. Regarding claim 13, Huang discloses an intervertebral disc prosthesis according to claim 1 above, however fails to disclose a coating on the outer surfaces of the half-shells. Errico et al. discloses an intervertebral disc prosthesis that comprises a coating on the outer surfaces of the half-shells (Paragraph [0110]) for ensuring primary osseous fixation. It therefore would have been obvious to one skilled in the art to modify the intervertebral disc prosthesis taught by Huang with the addition of a coating as is taught by Errico et al. because the coating provides the advantage of further aiding in bone fixation, while keeping the functional and structural features of the prosthesis analogous to that taught by Huang.

Regarding the above claims, see the figures corresponding to claim 1 and figure 1i in Errico et al.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELANA B. FISHER whose telephone number is (571)270-3643. The examiner can normally be reached on Monday through Friday from 8:30AM to 5:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571)272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Elana B Fisher/
Examiner, Art Unit 3733

/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733